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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,073	03/01/2002	Hartmut Beug	0652.1790001	3217

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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,073	BEUG ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 17 in part and 16, drawn to a pharmaceutical composition comprising an active compound a substance which inhibits the activity of TGFβ and an additional active compound a second substance which inhibits the expression of oncogenic Ras, classified in class 514, subclass 2-21.

II. Claims 17 in part and 16, drawn to a pharmaceutical composition comprising an active compound a substance which inhibits the activity of TGFβ and an additional active compound a second substance which inhibits the function of oncogenic Ras, classified in class 514, subclass 2-21.

III. Claims 17 in part and 16, drawn to a pharmaceutical composition comprising an active compound a substance which inhibits the activity of TGFβ and an additional active compound a second substance which inhibits the overexpression of oncogenic Ras, classified in class 514, subclass 2-21.

IV. Claims 17 in part and 16 and 18, 19, 20 and 21 drawn to a pharmaceutical composition comprising an active compound a substance which inhibits the activity of TGFβ and an additional active compound a second

substance which directly inhibits the activation of normal Ras, classified in class 514, subclass 2-21.

V. Claims 17 in part and 16, 19, 20 and 21 drawn to a pharmaceutical composition comprising an active compound a substance which inhibits the activity of TGFβ and an additional active compound a second substance which indirectly inhibits the activation of normal Ras, classified in class 514, subclass 2-21.

VI. Claims 22 and 23, drawn to a method of treating breast tumors comprising administering to a human the pharmaceutical composition, classified in class 514, subclass 2.

VII. Claims 22 and 24, drawn to a method of treating kidney cell carcinomas tumors comprising administering to a human the pharmaceutical composition, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-V represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Groups I, II and III recite a pharmaceutical composition comprising an active compound a substance which inhibits the activity of TGFβ, and an additional active compound a second substance which inhibits the "expression", "function" and "overexpression" of oncogenic Ras respectively. Groups IV and V recite a pharmaceutical composition

comprising an active compound a substance which inhibits the activity of TGFβ and an additional active compound a second substance which inhibits the activation of normal Ras "directly" and "indirectly", respectively. The composition required for inhibiting the "expression" of oncogenic Ras would be different from the composition required for inhibiting the "function" of oncogenic Ras which in turn would be different from the composition required for the "inhibition" of overexpression of oncogenic Ras. Similarly, the composition required to "directly" inhibit the activation of normal Ras would be different from the composition required to "indirectly" inhibit the activation of normal Ras. Thus, groups I-V, although classified similarly, are disclosed as distinct, unrelated in function, and/or made by and/or used in different methods and therefore, the claimed products are distinct. The examination of all groups would require different searches in U.S. patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus inventions I-V are patentably distinct.

The inventions of Groups VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Group VI and VII recite a method of comprising administering to a human the pharmaceutical composition in treating breast tumors and treating kidney cell carcinomas. The inventions of Groups VI and VII, although classified similarly, encompass independent and or distinct methods which differ at least in objectives, method steps, dosages, schedules used, response variables, and criteria for success. For example, the search and examination of method drawn to treating

breast tumors comprises distinctly different objectives, response variables, and criteria for success versus method drawn to treating kidney cell carcinomas. Not only is there the consideration of the prior art, but separate issues for treating these various types of cancerous conditions merit separate examinations for patentability determination. Thus, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

The inventions of Groups "I-IV" and the methods of Groups "VI and VII" are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the methods of Groups VI and VII are drawn to treating breast tumors and the kidney cell carcinomas using the pharmaceutical composition of Groups I-IV. The product of Groups I-IV can be used in either of Groups VI and VII which differ in their pathologies and treatment methods.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one

group is not required for another group, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi, Ph.D.
Ph: (571) 272-8789

LARRY R. HELMS, PH.D
PRIMARY EXAMINER